

REMARKS

Claims 1, 2-22 and 35-38 are pending. Claim 21 is amended. Support for amended claim 21 is found at [0085]. Claim 38 is added. Support for claim 38 is found at [0098]-[0099] and Figures 1 & 2.

Issues outstanding:

- Claims 6 and 21 are rejected as indefinite under 35 U.S.C. § 112 ¶ 2.
- Claims 1, 3-6, 13 and 18 are rejected under 35 U.S.C. § 102(b) as anticipated by Mita et al. (US Patent No. 5,561,109).
- Claims 1, 3-6, 11, 15-16 and 18-22 are rejected under 35 U.S.C. § 102(e) as anticipated by Ando et al. (US 2004/0018190, filed 11/22/01).
- Claims 1, 3-8, 11-13, 15, 20-22 and 35 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Wu et al. (US Patent No. 5,712,247, published 1/27/98).
- Claims 1, 3-7 and 11-22 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Kruzel et al. (US 2003/0096736, filed 5/7/02).

I. 35 U.S.C. § 112 ¶ 2

Claims 6 and 21 are rejected as indefinite under 35 U.S.C. § 112 ¶ 2.

Claim 6 has the limitation “wherein said lactoferrin can be human or bovine.” This tracks the Specification, *e.g.*, at [0045], and refers to lactoferrin derived from human or bovine sources or recombinant versions of the same. One of skill in the art reading claim 6 would not be confused as to its meaning.

Claim 21 is amended to clarify its meaning.

Applicant requests the Examiner withdraw the rejections in view of the above amendment and argument.

II. 35 U.S.C. § 102(b)

Claims 1, 3-6, 13 and 18 are rejected under 35 U.S.C. § 102(b) as anticipated by Mita et al. (US Patent No. 5,561,109).

Mita discloses the use of lactoferrin to treat eye inflammation induced corneal damage and promote corneal regeneration. Hence, Mita suggests use after ophthalmologic surgery to enhance post operative corneal healing. Mita does not address pain management. *See* Examiner's Office Action dated 12/29/05, ¶ 8.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP § 2112-IV; *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

The pending method relates to pain reduction in the context of surgical wound pain. The *in vivo* experiments disclosed in Mita are do not involve surgery. Hence, the Examiner cites Mita at col. 1, lines 35-67 for the sole Description reference to a surgical context. The Examiner reasons that the steps disclosed by Mita are the same and would result inherently yield pain reduction. *See* Examiner's Office Action dated 12/29/05, ¶ 8. However, not all ophthalmologic surgeries on the cornea result in pain in the subject (e.g. LASIK procedures). Thus, the steps in Mita for treating a subject postoperatively with lactoferrin to enhance corneal regeneration do not *necessarily* result in pain reduction in the subject. Because pain reduction may or may not occur using the steps disclosed in Mita, Mita cannot support an anticipation rejection.

Applicant requests the rejection be withdrawn.

III. 35 U.S.C. § 102(e)

Claims 1, 3-6, 11, 15-16 and 18-22 are rejected under 35 U.S.C. § 102(e) as anticipated by Ando et al. (US 2004/0018190, filed 11-22-01).

Ando is not anticipatory for reasons analogous to those for Mita above. The Description in Ando discloses use of lactoferrin to treat “a recurrence of gastric cancer after a surgical operation and retention of cancerous abdominal fluid.” In the example cited, the abdominal fluid resulted in pressure induced pain. The lactoferrin treatment of the abdominal illness ameliorated the abdominal fluid pressure and relieved the pain. However, “a patient suffering from a recurrence of gastric cancer after a surgical operation and retention of cancerous abdominal fluid” will not *necessarily* be in pain from either. Hence, the steps disclosed by Ando cannot anticipate the pending method claims.

Applicant requests the rejection be withdrawn.

IV. 35 U.S.C. § 103(a)

- a. Claims 1, 3-8, 11-13, 15, 20-22 and 35 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Wu et al. (US Patent No. 5,712,247, published 1/27/98).

All claim limitations must be taught or suggested for a *prima facie* case of obviousness. MPEP § 2143.03. The inherent teachings of a reference may be relied upon to provide an element or provide the suggestion to modify or combine prior art. MPEP § 2112. The Examiner cites the use of lactoferrin as an anticoagulant in Wu and argues “it would be obvious that the administration of lactoferrin would inherently provide an improvement in the pain associated with cardiovascular surgery...”

The Examiner is required to show one of skill in the art would recognize the alleged inherent element or suggestion. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1576, 230 USPQ 81, 88 (Fed. Cir. 1986) (“That argument is unpersuasive when confronted by Stora's failure to establish at trial that that inherency would have been obvious to those skilled

in the art when the invention of claim 4 was made. Inherency and obviousness are distinct concepts.”). The Examiner must support the rejection by explaining how and why one of skill in the art would ascertain the pain reduction properties of lactoferrin from the anticoagulant applications disclosed in Wu. Such an argument is not possible because the *in vitro* anticoagulation studies disclosed by Wu cannot be read to convey the pain reduction properties of lactoferrin to one of skill in the art. Thus, there would be no recognition by one of skill in the art of the pain reducing properties of lactoferrin to motivate one of skill to use lactoferrin for pain management.

Applicant requests the rejection be withdrawn.

- b. Claims 1, 3-7 and 11-22 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Kruzel et al. (US 2003/0096736, filed 5/7/02).

As with Wu above, the Examiner argues Kruzel would inherently inform one of skill in the art that lactoferrin treatment of cancer patients would also reduce associated cancer pain. The Examiner cannot, of course, establish a *prima facie* case by a conclusory allegation that “it would be obvious that the administration of lactoferrin would inherently provide an improvement in the pain associated with cancer.” *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). The Examiner must provide detailed reasoning for this conclusion. *Id.* The Examiner supports the motivation argument by citing Kruzel’s disclosed use of a dosage of lactoferrin allegedly within the scope pending claims. *See* Examiner’s Office Action dated 12/29/05, ¶ 11. This is may be a necessary predicate fact for the argument. But this fact alone does not explain how one of skill in the art, reading Kruzel, would deduce a suggestion to treat cancer related pain with lactoferrin. Applicant cannot understand what in Kruzel would inform one of skill in the art and thus motivate one of skill to perform the pending method claims.


Applicant requests the rejection be withdrawn.

In view of the above, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02705US2 from which the undersigned is authorized to draw.

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Respectfully submitted,

By  _____

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